

AMENDMENTS TO THE CLAIMS

1. (Currently amended) A method of administering testosterone to a mammal to provide transmucosal absorption of a pharmacologically effective amount of testosterone through the oral mucosa of the mammal to the systemic circulatory system of the mammal, comprising:

spraying the oral mucosa of the mammal with a buccal spray composition comprising in weight percent of the composition: testosterone or a pharmaceutically acceptable ester thereof in an amount of between 0.1 and 25 percent by weight of the total composition; a polar solvent in an amount between 10 and 97 percent by weight of the total composition; and a propellant in an amount between 2 and 10 percent by weight of the total composition, wherein said propellant is a C₃ to C₈ hydrocarbon of linear or branched configuration, wherein a ~~therapeutically~~ pharmacologically effective amount of testosterone is absorbed through the oral mucosa of the mammal to the mammal's systemic circulatory system.

2. (Previously presented) The method of claim 1, further comprising a taste mask and/or flavoring agent in an amount between 0.05 and 10 percent by weight of the total composition.

3. (Previously presented) The method of claim 2, wherein the polar solvent is present in an amount between 20 and 97 percent by weight of the total composition, the testosterone or a pharmaceutically acceptable ester thereof is present in an amount between 0.1 and 15 percent by weight of the total composition, the propellant is present in an amount between 2 and 5 percent by weight of the composition, and the taste mask and/or flavoring agent is present in an amount between 0.1 and 5 percent by weight of the total composition.

4. (Previously presented) The method of claim 3, wherein the polar solvent is present in an amount between 25 and 97 percent by weight of the total composition, the testosterone or a pharmaceutically acceptable ester thereof is present in an amount between 0.2 and 25 percent by weight of the total composition, the propellant is present in an amount between 2 and 4 percent by weight of the composition, and taste mask and/or flavoring agent is present in an amount between 0.1 and 2.5 percent by weight of the total composition.

5. (Previously presented) The method of claim 1, wherein the polar solvent is selected from the group consisting of polyethyleneglycols having a molecular weight between 400 and 1000, C₂ to C₈ mono- and poly-alcohols, and C₇ to C₁₈ alcohols of linear or branched configuration.

6. (Previously presented) The method of claim 5, wherein the polar solvent comprises polyethylene glycol.

7. (Previously presented) The method of claim 5, wherein the polar solvent comprises ethanol.

8. (Previously presented) The method of claim 2, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

9. (Previously presented) The method of claim 1, wherein the propellant is selected from the group consisting of propane, N-butane, iso-butane, N-pentane, iso-pentane, neo-pentane, and mixtures thereof.

10. (Previously presented) The method of claim 1, wherein the pharmaceutically acceptable ester of testosterone is selected from the group consisting of testosterone propionate, testosterone enanthate, and testosterone cypionate.

11. (Canceled).

12. (Previously presented) The method of claim 1, wherein the amount of the spray is predetermined.

Claims 13-29 (Canceled).

30. (Currently amended) A method of administering testosterone to a mammal to provide transmucosal absorption of a pharmacologically effective amount of testosterone through the oral mucosa of the mammal to the systemic circulatory system of the mammal, comprising:

spraying the oral mucosa of the mammal with a buccal spray composition comprising in weight percent of the composition: testosterone or a pharmaceutically acceptable ester thereof in an amount between 0.05 and 50 percent by weight of the total composition; a mixture of a polar and a non-polar solvent in an amount between 10 and 97 percent by weight of the total composition, wherein the ratio of the polar solvent to the non-polar solvent ranges from 1:99 to 99:1; and a propellant in an amount between 5 and 80 percent by weight of the total composition, wherein said propellant is a C₃ to C₈ hydrocarbon of linear or branched configuration, wherein a therapeutically pharmacologically effective amount of testosterone is absorbed through the oral mucosa of the mammal to the mammal's systemic circulatory system.

31. (Previously presented) The method of claim 30, wherein the composition further comprises a taste mask and/or flavoring agent is present in an amount between 0.01 and 10 percent by weight of the total composition.

32. (Previously presented) The method of claim 31, wherein the propellant is present in an amount between 10 and 70 percent by weight of the total composition, the solvent is present in an amount between 20 and 97 percent by weight of the total composition, the testosterone or a pharmaceutically acceptable ester thereof is present in an amount from between 0.1 and 40 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 1 and 8 percent by weight of the total composition.

33. (Previously presented) The method of claim 30, wherein the propellant is selected from the group consisting of propane, n-butane, iso-butane, n-pentane, iso-pentane, neo-pentane, and mixtures thereof.

34. (Previously presented) The method of claim 33, wherein the propellant is n-butane or iso-butane and has a water content of not more than 0.2 percent and a concentration of oxidizing agents, reducing agents, Lewis acids, and Lewis bases of less than 0.1 percent.

35. (Previously presented) The method of claim 30, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and

1000, C₂ to C₈ mono- and poly-alcohols, and C₇ to C₁₈ alcohols of linear or branched configuration and the non-polar solvent is selected from the group consisting of (C₂-C₂₄) fatty acid (C₂-C₆) esters, C₇-C₁₈ hydrocarbons of linear or branched configuration, C₂-C₆ alkanoyl esters, and triglycerides of C₂-C₆ carboxylic acids.

36. (Previously presented) The method of claim 30, wherein the pharmaceutically acceptable ester of testosterone is selected from the group consisting of testosterone propionate, testosterone enanthate, and testosterone cypionate.

37. (Canceled).

38. (Previously presented) The method of claim 30, wherein the amount of the spray is predetermined.

Claims 39-74. (Canceled).